

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/980,881	MATSUMOTO, AKIRA	
	<b>Examiner</b>	<b>Art Unit</b>	
	Sheridan L. Swope	1652	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to April 29, 2005.
2. ☒ The allowed claim(s) is/are 3-7,9,11,16,18-20,24-26,32 and 34-44.
3. ☒ The drawings filed on 30 October 2001 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☒ Some\*    c) ☐ None    of the:
  1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: JAPAN 11/125169.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |  |
|--|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date <u>0405</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                    |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material                           | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|  | 9. <input type="checkbox"/> Other _____.   |

### DETAILED ACTION

Applicant's response, on April 29, 2005, to the Final Rejection of this case, mailed November 29, 2004, is acknowledged. It is acknowledged that applicants have amended Claims 20, 37, 38, 39, 41, and 43. Claims 3-7, 9, 11, 16, 18-20, 24-26, 32, and 34-44 are pending and are hereby reconsidered.

#### *Examiner's Amendment*

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Replace Claim 37 with the following.

37. An isolated peptide fragment of human brain carboxypeptidase B consisting of at least 7 contiguous amino acids of SEQ ID NO: 9, wherein the peptide binds to an antibody to a protein having the amino acid sequence of SEQ ID NO: 2.

For Claim 38, line 2, delete –consisting of an epitope of human brain carboxypeptidase B–.

For Claim 39, replace lines 3-6 with the following:

(a) contacting a test sample with a peptide fragment of human brain carboxypeptidase B consisting of at least 7 contiguous amino acids of SEQ ID NO: 9, wherein the peptide binds to an antibody to a protein having the amino acid sequence of SEQ ID NO:2;

For Claim 40, line 3-4, delete –consisting of an epitope of human brain carboxypeptidase B–.

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Authorization for this examiner's amendment was given in a telephone interview with Mark Sandbaken on May 17, 2005.

***Allowable Subject Matter***

Claims 3-7, 9, 11, 16, 18-20, 24-26, 32, and 34-44 are allowed.

The following is an examiner's statement of reasons for allowance:

All elected Claims, 3-7, 9, 11, 16, 18-20, 24-26, 32, and 34-44, are limited to polypeptides having peptidase activity towards brain APP wherein said polypeptides are encoded by SEQ ID NO: 1, or set forth by SEQ ID NOs: 2, 3, or 4, or variants or fragments thereof.

The closest prior art, to the proteins set forth by SEQ ID NO: 2, 3, and 4, is Eaton et al, 1991. The protein of Eaton et al has 94%, 94%, and 93% identity with SEQ ID NO: 2, 3, and 4, respectively. However, the protein of Eaton et al does not appear to be any of the proteins set forth by SEQ ID NO: 2, 3, or 4 because the protein of Eaton has an insert comprising 37 residues, while SEQ ID NO: 2, 3, and 4 do not have said insert. In addition, SEQ ID NO: 2, 3, and 4 have a C-terminal tail of 14 residues, consisting of SNPPVEKLLPLSLK, that differs from the protein of Eaton et al. In place of said C-terminal tail, the protein of Eaton et al has a C-terminal region of 40 residues that differs from SEQ ID NO: 2, 3, and 4. Therefore, it is concluded that Eaton et al is not any of the proteins set forth by SEQ ID NO: 2, 3, and 4, nor within the scope of variants recited.

The utility of the proteins set forth by SEQ ID NO: 2, 3, and 4, as having peptidase activity towards brain APP, is credible based on purification of proteins with said activity from human brain, peptide sequencing, PCR cloning of the encoding polynucleotide, and DNA sequencing (Examples 1, 2, and 7).

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Sheridan Lee Swope, Ph.D.



REBECCA E. PROUTY  
PRIMARY EXAMINER  
~~GROUP 1800~~

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